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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,610	10/13/2006	Austen Peter Bradley	58412.5	7803
27128	7590	12/24/2008		
HUSCH BLACKWELL SANDERS LLP			EXAMINER	
720 OLIVE STREET			D'ANGELO, MICHAEL J	
SUITE 2400				
ST. LOUIS, MO 63101			ART UNIT	PAPER NUMBER
			4185	
			NOTIFICATION DATE	DELIVERY MODE
			12/24/2008	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

[pto-sl@huschblackwell.com](mailto:pto-sl@huschblackwell.com)

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/598,610	BRADLEY, AUSTEN PETER
	<b>Examiner</b>	<b>Art Unit</b>
	MICHAEL D'ANGELO	4185

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 06 June 2006.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-18 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-18 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 09/06/2006 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>09/06/2006</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|   | 6) <input type="checkbox"/> Other: _____ .                        |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 7-12, 14 and 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Mault (US 2002/173728).

**Regarding claim 1**, Mault discloses a means to measure a volume of inhaled breath *flow meter-14*; and a means to measure the gas content of exhaled breath component (*gas concentration sensor-26*).

**Regarding claim 2**, Mault discloses a calorimeter (column 7, line 1).

**Regarding claim 3**, Mault discloses a flow meter (*flow meter-14*).

**Regarding claim 7**, Mault discloses a mass flow meter (paragraph 22, line 5)

**Regarding claim 8**, Mault discloses an oxygen and carbon dioxide sensor (paragraph 29, lines 13-14).

**Regarding claim 9**, Mault discloses an opening in the housing to allow for inhaling external fluid (*gas inlet one way valve-76*).

**Regarding claim 10**, Mault discloses calculating the respiratory oxygen consumption (abstract, lines 1-2).

**Regarding claim 11-12,** Mault discloses calculating/measuring a volume of inhaled breaths and the gas content of exhaled breaths (claim 1, paragraph 5).

**Regarding claim 14,** Mault discloses calculating/measuring a volume of inhaled breaths and the gas content of exhaled breaths (claim 1, paragraph 5) and a means to measure a volume of inhaled breath *flow meter-14*; and a means to measure the gas content of exhaled breath *component (gas concentration sensor-26)*.

**Regarding claim 16,** Mault discloses calculating/measuring a volume of inhaled breaths and the gas content of exhaled breaths (claim 1, paragraph 5) and an oxygen and carbon dioxide sensor (paragraph 29, lines 13-14).

**Regarding claim 17,** Mault discloses calculating/measuring a volume of inhaled breaths and the gas content of exhaled breaths (claim 1, paragraph 5) and an opening in the housing to allow for inhaling external fluid (*gas inlet one way valve-76*).

**Regarding claim 18,** Mault discloses calculating/measuring a volume of inhaled breaths and the gas content of exhaled breaths (claim 1, paragraph 5) and calculating the respiratory oxygen consumption (abstract, lines 1-2).

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mault

(US 2002/0173728) in view of Yasushi et al. (6,485,418).

**Regarding claim 13,** Mault discloses measuring a volume of an inhaled breath and the gas content of an exhaled breath (claim 1, paragraph 5), but fails to disclose storing the measurements as a reference and then comparing new measurements to the reference.

However, Yasushi et al. discloses storing the measurements as a reference and then comparing new measurements to the reference column 5, lines 67 and column 6, lines 4).

6. It would have been obvious to one of ordinary skill in the art to modify the teachings of Mault to include storing the measurements as a reference and then comparing new measurements to the reference as taught by Yasushi et al. Doing so would allow the disclosed invention to have a calibration feature and therefore take more accurate readings.

7. Claims 4-6, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mault (US 2002/0173728) in view of Jones, Jr. et al. (US 5,076,093).

**Regarding claim 4,** Mault discloses a flow meter (14), but fails to disclose a moveable member.

However, Jones, Jr. et al. discloses a moveable member *piston-12* and an associated sensor *sensor assembly-13*.

8. It would have been obvious to one of ordinary skill in the art to modify the teachings of Mault with a moveable member associated with the sensor as taught by Jones, Jr. et al. Doing so would allow for a mechanical flow measuring means to be compared to the flow meter disclosed. This would allow for more accurate volume measurement and higher precision.

**Regarding claim 5,** Mault fails to disclose a plunger slideably mounted within the housing.

However, Jones, Jr. et al. discloses a plunger *piston-12* slideably mounted within the housing (column 1, lines 62-64, view figure).

9. It would have been obvious to one of ordinary skill in the art to modify the teachings of Mault to include a slideably mounted plunger as taught by Jones, Jr. et al. Doing so would allow for easy movement of the plunger and a smooth and accurate reading by the flow sensor.

**Regarding claim 6,** Mault fails to disclose a fluid-tight contact between the plunger and housing.

However, Jones, Jr. et al. discloses fluid-tight contact between the plunger and the inner surface of the housing (Column 3, lines 59-63).

10. It would have been obvious to one of ordinary skill in the art to modify the teachings of Mault to incorporate a fluid-tight contact as taught by Jones, Jr. et al. Doing so would ensure that no gas is escaping between the housing and the plunger making the most accurate reading possible.

**Regarding claim 15,** Mault discloses calculating/measuring a volume of inhaled breaths and the gas content of exhaled breaths (claim 1, paragraph 5), but fails to disclose a fluid-tight contact between the plunger and housing.

However, Jones, Jr. et al. discloses fluid-tight contact between the plunger and the inner surface of the housing (Column 3, lines 59-63).

11. It would have been obvious to one of ordinary skill in the art to modify the teachings of Mault to incorporate a fluid-tight contact as taught by Jones, Jr. et al. Doing so would ensure that no gas is escaping between the housing and the plunger making the most accurate reading possible.

### ***Conclusion***

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Review form 892-Notice of References Cited.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL D'ANGELO whose telephone number is (571) 270-7112. The examiner can normally be reached on Monday-friday 9-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrell McKinnon can be reached on (571) 272-4797. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MICHAEL D'ANGELO/  
Examiner, Art Unit 4185

/Terrell L Mckinnon/  
Supervisory Patent Examiner, Art Unit 4185